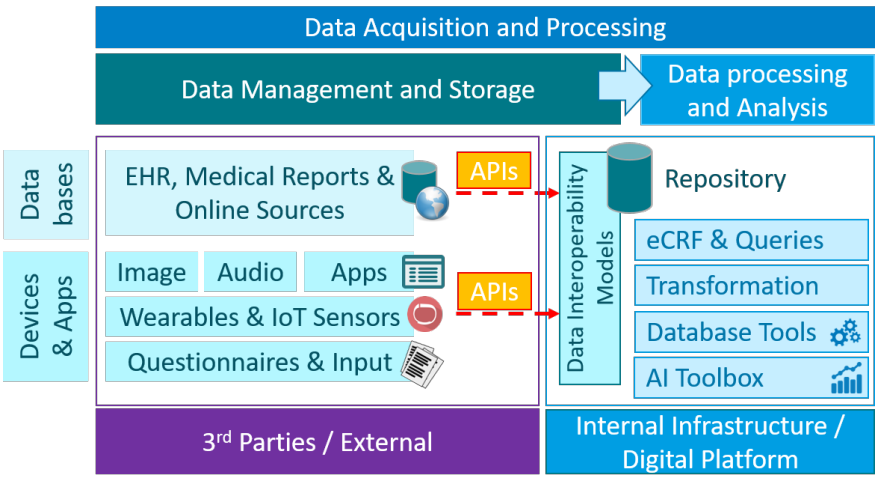
Basic Building Block Profile

Building Block: Data Acquisition and Processing

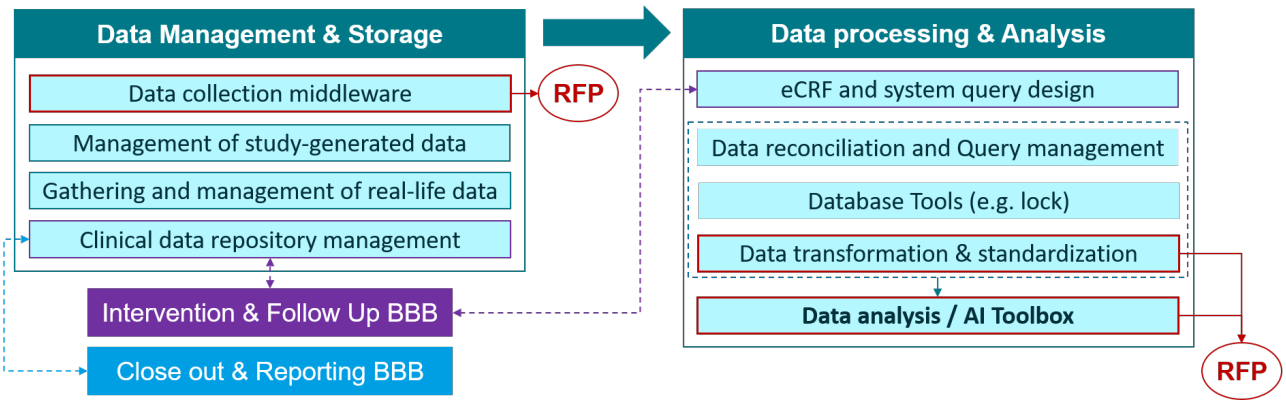
Vision

The Data acquisition and Processing Basic Building Block contains activities related to data acquisition and processing of acquired data. The vision includes **A) Data Collection, Management and Storage** of different data sources to an internal infrastructure. This category includes activities in which all study data are stored and managed. Both patient's and clinician's perspectives are taken into consideration. Both general Data bases and devices/apps data categories are going to be integrated using appropriate well-defined Application Programming Interfaces (APIs), through secure user authentication/authorization (OAuth protocol) and will be stored in the internal interoperable repository infrastructure, ensuring that data privacy and quality standards are met. In the next phase comes the **B) Processing and Analysis**, including activities in which data are checked, verified, transformed, and analysed. The RDCT concept is fully supported by service-oriented modular and remotely accessibly design: accessing data sources remotely through API web services and the infrastructure, as well as through data visualizations.



The research leading to these results has received support from the EU/EFPIA Innovative Medicines Initiative [2] Joint Undertaking (H2020-JTI-IMI2) Trials@Home grant n° 831458.

Activities



Included activities in the RFP

The following activities are included in the RFP:

Data Collection Middleware Technology

Middleware Technology system for active and passive data collection from data sources that will include monitoring devices, wearables, sensors and apps.

*Devices that might be used in the Pilot Study and will require such middleware:

- Smart dosing insulin pen device
- Continuous glucose monitoring device
- Insulin titration support app
- Adherence data capture app
- etc.

Data Transformation and Standardization

Capabilities for converting data from one format or structure into another format or structure via a mixture of manual and automated steps.

Data Analysis

Statistical testing for the protocol's underlying hypotheses and Analytics capabilites also by making use of AI technology - retrospective, statistic analysis, clustering etc.

Excluded activities from the RFP

The activities below are already covered by internal partners and **excluded from the RFP**:

- Management of study-generated data
- Gathering and management of real-life data
- Clinical data repository management
- eCRF and system query design
- Data reconciliation and Query management
- Database Tools (e.g. lock)

The research leading to these results has received support from the EU/EFPIA Innovative Medicines Initiative [2] Joint Undertaking (H2020-JTI-IMI2) Trials@Home grant n° 831458.

RFP – Knockout Criteria

For the activities included in the RFP we have identified a number of knockout criteria that will exclude the technology vendor in the case that one or more of them are not met.

Data Collection Middleware Technology

The technology will be rejected if:

1) Data integration capabilities with Clinpal and other selected internal or external systems are missing (e.g. appropriate APIs)
2) Multiple data sources collection is not supported (*monitoring devices, wearables, sensors and apps*)
3) Not compliant with Data Quality and Data Privacy regulations

Data Transformation and Standardisation

The technology will be rejected if:

1) Data integration capabilities with Clinpal and other selected internal or external systems are missing (e.g. appropriate APIs)
2) Multiple data sources are not supported
3) Not compliant with Data Quality and Data Privacy regulations

Data Analysis

The technology will be rejected if

1) Data integration capabilities with other internal or external systems are missing (e.g. appropriate APIs)
2) Analytics capabilities, streaming analytics (e.g. for devices), “Business” Intelligence and Reporting capabilities are not present
3) Not compliant with Data Quality and Data Privacy regulations

The research leading to these results has received support from the EU/EFPIA Innovative Medicines Initiative [2] Joint Undertaking (H2020-JTI-IMI2) Trials@Home grant n° 831458.